

December 10, 2020

Mary Smith
115 Happy Lane
Joyville, USA 11223

Dear Ms. Smith,

We are writing to let you know about a potential infection risk linked to a machine that was used to cool and heat your body during your recent heart operation at Beth Israel Deaconess Medical Center (BIDMC). Our records indicate that you underwent open heart surgery at BIDMC between January and May 2020, and as a result, you may be affected. As described more below, your risk of infection is very low; however, we are contacting you as a precaution to inform you about this development and symptoms to notify your provider about, if they occur.

BIDMC has identified a small number of infections among patients who underwent open heart surgery between February and March 2020. The infection is linked to a type of bacteria called *Mycobacterium abscessus*, also known as nontuberculous mycobacterium. We immediately launched a thorough investigation and found that the infection was associated with the use of the CardioQuip Modular Cooler-Heater Device, a device used by hospitals across the nation to heat and cool the blood during surgery. An international outbreak of another type of nontuberculous mycobacteria was reported with a different heater-cooler device in 2015.

Working closely with your surgeon, BIDMC has been partnering with the Massachusetts Department of Public Health, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in this investigation. The FDA recently issued a Letter to Health Care Providers about this event to alert other clinicians to potential risks in their facilities. Beth Israel Deaconess Medical Center acted quickly after identifying this issue and removed the CardioQuip Modular Cooler-Heater Devices from our operating rooms.

We want to reassure you that the risk that you will be affected by this rare infection is very low. The CDC estimates the risk of infection associated with these types of machines to be less than 1 percent. Given that most patients who are infected develop symptoms within the first few months, the risk is even lower if you are asymptomatic, now more than six months out from your procedure.

That said, we felt it was important to notify you, as the infection associated with this device is very slow-growing and can be difficult to diagnose. In extremely rare cases, symptoms can develop years after surgery, so it is important to know the symptoms. While the likelihood of infection is very low, the most common site of occurrence has been at the surgical incision (on the chest). More general symptoms of this infection include:

- night sweats
- muscle aches
- weight loss

- fatigue
- unexplained fever

Importantly, this type of infection cannot be spread from person-to-person. You do not need to take any precautions or undergo any treatment at this time. We encourage you to discuss any symptoms or questions you may have with your primary care doctor and/or cardiologist.

We understand that you and your family may have additional questions or concerns. We have established a special phone line to respond to your specific questions, and we invite you to call (617) 975-9770. You can also find more information on our website at <https://www.bidmc.org/cardiocrisk> and on the CDC and FDA websites:


CDC: <https://www.cdc.gov/HAI/outbreaks/heater-cooler.html>

FDA: <https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-infection-during-cardiac-surgery-when-using-cardioquip-modular-cooler-heater-device>

Sincerely,



Cheryle Totte, RN, MS
Director, Patient Safety



Sharon B. Wright MD, MPH
Senior Medical Director, Infection Control/Hospital Epidemiology



Anthony P. Weiss, MD, MBA, MSc
Chief Medical Officer